DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2015

TECO DIAGNOSTICS
AQUIL MERCHANT
RESEARCH SCIENTIST
1268 NORTH LAKEVIEW AVE.
ANAHEIM CA 92807

Re: K141289
Trade/Device Name: TC-Thunderbolt Automated Urine Analyzer System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: II
Product Code: JIL, JIO, KQO, LJX, JRE, CEN, JMT, JIR, JIN, CDM, JJB
Dated: July 17, 2015
Received: July 20, 2015

Dear Mr. Merchant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k141289

Device Name
TC-Thunderbolt Automated Urine Analyzer System

Indications for Use *(Describe)*
The TC-Thunderbolt Automated Urine Analyzer System is an in vitro diagnostic device used to automate the urine chemistry analysis using TC-Thunderbolt URS-10 strips. It produces semi-quantitative results of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity and leukocytes in urine. TC-Thunderbolt URS-10 strips are intended for use only with TC-Thunderbolt Automated Urine Analyzer System, they are not intended for manual visual reading. This device is for clinical laboratory use only. This device is not for Point of Care Use. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Applicant:
510(k) Number: k141289
Teco Diagnostics
1268 N. Lakeview Avenue
Anaheim, CA 92807

Aquil Merchant, M.S., Research Scientist
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Date: 07/24/2015

4.1) TC-Thunderbolt Automated Urine Analyzer System:

A) Proprietary and Established Names:

Proprietary Names: TC-Thunderbolt Automated Urine Analyzer System

Common Names: Automated Urine Analyzer, Urine Test System (non-quantitative).
The system consists of the TC-Thunderbolt Automated Urine Analyzer and the TC-Thunderbolt URS-10 strips.

4.2) Regulatory Information:

Regulation section	Code	Test	Classification
21 CFR § 862.1340	JIL	Urinary Glucose (nonquantitative) Test System	II
21 CFR § 864.6550	JIO	Occult Blood Test	II
21 CFR § 862.2900	KQO	Automated Urinalysis System	I
21 CFR § 864.7675	LJX	Leukocyte Peroxidase Test	I
21 CFR § 862.2800	JRE	Refractometer for clinical use	I
21 CFR § 862.1550	CEN	Urinary pH (nonquantitative) Test System	I
21 CFR § 862.1510	JMT	Nitrite (nonquantitative) Test System	I
21 CFR § 862.1645	JIR	Urinary Protein or Albumin (nonquantitative) Test System	I
21 CFR § 862.1435	JIN	Ketones (nonquantitative) Test System	I
21 CFR § 862.1785	CDM	Urinary Urobilinogen (nonquantitative) Test System	I
21 CFR § 862.1115	JJB	Urinary Bilirubin and its conjugates (nonquantitative) Test System	I

4.3) Indication for Use:

The TC-Thunderbolt Automated Urine Analyzer System is an in vitro diagnostic device used to automate the urine chemistry analysis using TC-Thunderbolt URS-10 strips. It produces semi-quantitative results of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity and leukocytes in urine. TC-Thunderbolt URS-10 strips are intended for use only with TC-Thunderbolt Automated Urine Analyzer System, they are not intended for manual visual reading. This device is for clinical laboratory use only. This device is not for Point of Care Use. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

4.4) Predicate Device:

Uritek-720+ Urine Analyzer for the use with Teco Diagnostic's URS-10 strips (k051526).

4.5) Description of the proposed device:

The proposed device is an automated urine chemistry analyzer system intended for use only with TC-Thunderbolt URS-10 strips for the measurement of ten urine chemistry analytes from the chemistry strip. The system consists of the TC-Thunderbolt Automated Urine Analyzer and the TC-Thunderbolt URS-10 strips.

4.6) TC-Thunderbolt Automated Urine Analyzer System v/s Uritek-720+ Analyzer:

Description	Proposed	Predicate
Device	TC-Thunderbolt Automated Urine Analyzer System	Uritek-720+ Analyzer
Intended Use	Automated Urine Chemistry Analyzer used for in vitro measurement of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity and leukocytes in urine.	Same
Design	Same as predicate	Uses proven chemical test method protocol for the intended use determinations of all 10 parameters
Design	Same as predicate	Uses the principle of light reflection to determine the color intensity on reagent strip test area
Design	Same as predicate	Uses testing technology of a cold light source, integrating sphere and modularized blocking systematical design which enhances the stability of the optical system
Design	The test module uses the principle of light-reflection to determine the changes in paper color, conduct a digital analysis on the central portion most uniform in color of the paper	Measures the color intensity by irradiating the white light and detecting the reflectance on the urine pad with an integrated sphere photo-detector

Testing Pattern	The test module uses automatic sample-suction, strip advance, and sample-application technologies instead of manual operations to facilitate urinalysis. Transfer of urine sample takes place via a sample-suction needle and pipe which extracts and applies the sample to the test strip	The test strip needs to be dipped in the test tube containing urine sample manually. Dry the strip on an absorbent piece of paper and place it on the test table.
Safety	The device has been certified to comply with the latest applicable safety standards which includes EN 61010-1:2010 for LVD and EN 61010-2-101: 2002 for IVD	The device has been certified to comply with the latest applicable safety standards which includes EN 61010-1:2010 for LVD and EN 61010-2-101: 2002 for IVD
Electromagnetic Compatibility	The proposed device has been tested and certified to EN 61326-1:2006 EMC requirements-general, EN 61326-2-6:2006 EMC requirements-particular requirements for IVD medical equipment, EN 61000-3-2:2006 + A1:2009 + A2: 2009 and EN 61000-3-3:2008	The device has been tested and certified to EN 61000-4-2, EN 61000-4-4, EN 61000-4-5 and EN 61000-4-11
Chemistry Strips	The TC-Thunderbolt Automated Urine Analyzer System is intended for use only with TC-Thunderbolt URS-10 strips	The Uritek-720+ analyzer is intended for use only with Teco Diagnostic's URS 10 strips

The TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ analyzer share the same technological characteristics including the testing parameters, print out, calibration method, and power requirements. The most notable difference is in their respective testing patterns, wherein TC-Thunderbolt Automated Urine Analyzer System uses automatic sample-suction, strip advance, and sample-application technologies and for the predicate the test strip needs to be dipped in urine sample and placed on the test table manually. In addition to this, they also differ in their display, user interface, entered parameter (user ID), dimensions and weight. These differences do not have any effect on the results or operations of the devices since the color development and reflectance values are measured after one minute.

4.7) TC-Thunderbolt Automated Urine Analyzer System v/s Teco Diagnostic's URS-10 Strips:

Description	TC-Thunderbolt Automated Urine Analyzer System	Teco Diagnostic's URS-10 Strips
Intended Specimen	Urine	Same
Materials Provided	Plastic strips affixed with reagent pads	Same
Dimension	110mm (length) x 5mm (width)	108mm (length) x 5mm (width)
Glucose Methodology	Based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the reaction in which glucose is oxidized to produce gluconic acid and hydrogen peroxide. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen in which the chromogen is oxidized to different colors ranging from blue-green to greenish-brown through brown and dark brown.	Same
Bilirubin Methodology	Based on the coupling of bilirubin with a diazotized dichioroaniline in a strongly acid medium. Varying bilirubin levels will produce light tan to reddish brown color proportional to its concentration in urine.	Same
Ketone Methodology	Based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.	Same
Specific Gravity Methodology	Based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.	Same
Blood Methodology	Based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3', 5, 5 '-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.	Same
pH Methodology	Based on the well-known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.	Same

Protein Methodology	Based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to blue-green for a "Positive" reaction.	Same
Urobilinogen Methodology	Based on a modified Ehrlich reaction in which p-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.	Same
Nitrite Methodology	This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with p-arsanilic acid to from a diazonium compound in an acid medium. The diazoniumn compound in turn couples with 1, 2, 3, 4- tetrahydrobenzo (h) quinolin to produce a pink color.	Same
Leukocyte Methodology	Based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazoniumn salt to produce a beige-pink to purple color.	Same

The TC-Thunderbolt URS-10 Strips and Teco Diagnostic's URS-10 strips share the same characteristics including Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte methodologies. The differences between the TC-Thunderbolt URS-10 Strips and Teco Diagnostic's URS-10 strips could be the length of the strip, paper of reagent pad and black plastic pad. The TC-Thunderbolt URS-10 strips are 2mm longer in length and have a black plastic pad at the end which is meant only for alignment purpose in the TC-Thunderbolt Automated Urine Analyzer System. However these differences do not have any effect on the results or operations of the devices.

4.8) Test Principle:

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the reaction in which glucose is oxidized to produce gluconic acid and hydrogen peroxide. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen in which the chromogen is oxidized to different colors ranging from blue-green to greenish-brown through brown and dark brown.

Bilirubin: This test is based on the coupling of bilirubin with a diazotized dichioroaniline in a strongly acid medium. Varying bilirubin levels will produce light tan to reddish brown color proportional to its concentration in urine.

Ketone: This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or

blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.

Blood: This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3', 5, 5 '-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

pH: This test is based on the well-known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

Protein: This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to blue-green for a "Positive" reaction.

Urobilinogen: This test is based on a modified Ehrlich reaction in which p-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with p-arsanilic acid to from a diazonium compound in an acid medium. The diazoniumn compound in turn couples with 1, 2, 3, 4- tetrahydrobenzo(h) quinolin to produce a pink color.

Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazoniumn salt to produce a beige-pink to purple color.

4.9) Analytical Performance Studies

A) Precision Study Summary:

- *Within Run:*

  Repeatability (within run and day-to-day) precision of the TC-Thunderbolt Automated Urine Analyzer System was evaluated using commercially available urine control solutions at Level I (High analyte concentration), Level II (Low analyte concentration) and Level III (Negative). The package insert and certificate of analysis of these control solutions confirmed the specific target analyte concentration in each level. 20 replicate assays of each level (negative, low positive, and high positive) were analyzed on TC-Thunderbolt Automated Urine Analyzer with three lots of TC-Thunderbolt URS-10 strips by three operators. A total of 60 strips were used for each level control solution tested (20 strips x 1 day x 3 operators/strip lots = 60 tests per control). The results from the Within Run Precision study are summarized below:

Urine Control Level I

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	500 mg/dL	58/60	96.67	60/60	100	60
Bilirubin	Moderate	60/60	100	60/60	100	60
Ketone	40 mg/dL	60/60	100	60/60	100	60

Specific Gravity	1.015	60/60	100	60/60	100	60
Blood	Moderate	59/60	98.34	60/60	100	60
Nitrite	Positive	60/60	100	60/60	100	60
Protein	300 mg/dL	60/60	100	60/60	100	60
Urobilinogen	8 EU/dL	60/60	100	60/60	100	60
Leukocyte	Moderate	60/60	100	60/60	100	60
pH	7.5	60/60	100	60/60	100	60

Urine Control Level II

Analyte	Level	Exact Match Agreement	%Agreement (Exact Match)	+/- Color Block Agreement	%Agreement (+/- Color Block)	N
Glucose	100 mg/dL	58/60	96.67	60/60	100	60
Bilirubin	Small	60/60	100	60/60	100	60
Ketone	40 mg/dL	59/60	98.83	60/60	100	60
Specific Gravity	1.015	57/60	95	60/60	100	60
Blood	Trace	59/60	100	60/60	100	60
Nitrite	Positive	60/60	100	60/60	100	60
Protein	Negative	60/60	100	60/60	100	60
Urobilinogen	0.2 EU/dL	60/60	100	60/60	100	60
Leukocyte	Small	60/60	100	60/60	100	60
pH	7.5	60/60	100	60/60	100	60

Urine Control Level III

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	Negative	60/60	100	60/60	100	60
Bilirubin	Negative	60/60	100	60/60	100	60
Ketone	Negative	59/60	100	60/60	100	60
Specific Gravity	1.005	58/60	96.67	60/60	100	60
Blood	Negative	59/60	100	60/60	100	60
Nitrite	Negative	60/60	100	60/60	100	60
Protein	Negative	60/60	100	60/60	100	60
Urobilinogen	0.2 EU/dL	60/60	100	60/60	100	60
Leukocyte	Negative	60/60	100	60/60	100	60
pH	6.5	58/60	96.67	60/60	100	60

- *Run to Run:*

  TC-Thunderbolt Automated Urine Analyzer was evaluated by testing each control level (negative, low positive, and high positive) by three operators with three lots of TC-Thunderbolt URS-10 strips in two replicate assays for 2 non- consecutive runs/day over 5 days. Run 1 and Run 2 were separated by atleast 1 hour. A total of 60 strips were used for each level control solution tested (2 strips x 2 run x 5 days x 3 operators/ strip lots = 60 tests per control). The results from the Run to Run Precision study are summarized below:

Urine Control Level I

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	500 mg/dL	60/60	100	60/60	100	60
Bilirubin	Moderate	60/60	100	60/60	100	60
Ketone	40 mg/dL	60/60	100	60/60	100	60
Specific Gravity	1.015	59/60	98.83	60/60	100	60
Blood	Moderate	59/60	100	60/60	100	60
Nitrite	Positive	60/60	100	60/60	100	60
Protein	300 mg/dL	60/60	100	60/60	100	60
Urobilinogen	8 EU/dL	59/60	98.83	60/60	100	60
Leukocyte	Moderate	60/60	100	60/60	100	60
pH	7.5	60/60	100	60/60	100	60

Urine Control Level II

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	100 mg/dL	60/60	100	60/60	100	60
Bilirubin	Small	60/60	100	60/60	100	60
Ketone	40 mg/dL	60/60	100	60/60	100	60
Specific Gravity	1.015	56/60	93.34	60/60	100	60
Blood	Trace	59/60	100	60/60	100	60
Nitrite	Positive	60/60	100	60/60	100	60
Protein	Negative	60/60	100	60/60	100	60
Urobilinogen	0.2 EU/dL	60/60	100	60/60	100	60
Leukocyte	Small	58/60	96.67	60/60	100	60
pH	7.5	60/60	100	60/60	100	60

Urine Control Level III

Analyte	Level	Exact Match Agreement	% Agreement (Exact Match)	+/- Color Block Agreement	% Agreement (+/- Color Block)	N
Glucose	Negative	60/60	100	60/60	100	60
Bilirubin	Negative	60/60	100	60/60	100	60
Ketone	Negative	60/60	100	60/60	100	60
Specific Gravity	1.005	60/60	100	60/60	100	60
Blood	Negative	60/60	100	60/60	100	60
Nitrite	Negative	60/60	100	60/60	100	60
Protein	Negative	60/60	100	60/60	100	60
Urobilinogen	0.2 EU/dL	60/60	100	60/60	100	60
Leukocyte	Negative	60/60	100	60/60	100	60
pH	6.5	60/60	100	60/60	100	60

B) Method Comparison Study Summary:

This comparison study testing was performed at Teco Diagnostics, Anaheim CA in United States. The urine samples for analysis in these method comparison studies were provided by external clinical sites. Samples were collected within 4 hours of testing if maintained at room temperature or were stored for up to 8 hours prior to testing if maintained at 2-8°C. In order to obtain a desired range of abnormal values a pool of negative urine samples were spiked to elevated level with the analytes to be evaluated. These spiked samples represent 10% of the total samples tested. For each chemistry analyte, the values obtained for the individual urine samples were referred to the respective cut-off values for each system to discriminate between the negative (normal) and positive (abnormal) findings, if applicable. The data was represented in concordance charts showing percent exact match agreement and percent agreement within 1 color block.

Glucose						
Thunderbolt / Uritek-720+	1000	500	250	100	Neg	Overall
1000	11					
500		19	4			
250		3	22	1		
100				4		
Neg					423	
Total	11	22	26	5	423	487
% Agreement (Exact Match)	100.00	86.36	84.62	80.00	100.00	98.36
% Agreement (+/- Color Block)	100.00	100.00	100.00	100.00	100.00	100.00

Glucose concentration levels compared at a 98.36% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

Bilirubin					
Thunderbolt / Uritek-720+	3+	2+	1+	Neg	Overall
3+	6				
2+		7			
1+			40		
Neg			2	432	
Total	6	7	42	432	487
% Agreement (Exact Match)	100.00	100.00	95.24	100.00	99.59
% Agreement (+/- Color Block)	100.00	100.00	100.00	100.00	100.00

Bilirubin concentration levels compared at a 99.59% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

Ketone						
Thunderbolt / Uritek-720+	80	40	15	TRA	Neg	Overall
80	6					
40		10	3			
15		3	25	2		
TRA			2	14	1	
Neg					421	
Total	6	13	30	16	422	487
% Agreement (Exact Match)	100.00	76.92	83.33	87.50	99.76	97.74
% Agreement (+/- Color Block)	100.00	100.00	100.00	100.00	100.00	100.00

Ketone concentration levels compared at a 97.74% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

Specific Gravity							
Thunderbolt / Uritek-720+	>1.030	1.025	1.020	1.015	1.010	<1.005	Overall
>1.030	9	1					
1.025	3	118	12				
1.020		5	44	4			
1.015			7	101	3	2	
1.010				30	68	5	
<1.005				2	24	49	
Total	12	124	63	137	95	56	487
% Agreement (Exact Match)	75.00	95.16	69.84	73.72	71.58	87.50	79.88
% Agreement (+/- Color Block)	100.00	100.00	100.00	98.54	100.00	96.43	99.18

Specific Gravity concentration levels compared at a 79.88% overall exact match and a 99.18% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer. *The Acceptance Criteria for SG is +/- 0.005.

Blood						
Thunderbolt / Uritek-720+	3+	2+	1+	TRA	Neg	Overall
3+	13	3				
2+	1	45	6			
1+		4	20	5		
TRA				17	1	
Neg				2	370	
Total	14	52	26	24	371	487
% Agreement (Exact Match)	92.86	86.54	76.92	70.83	99.73	95.48
% Agreement (+/- Color Block)	100.00	100.00	100.00	100.00	100.00	100.00

Blood concentration levels compared at a 95.48% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

Protein						
Thunderbolt / Uritek-720+	>300	100	30	TRA	Neg	Overall
>300	40	3				
100	3	32				
30			17			
TRA			3	20		
Neg				1	368	
Total	43	35	20	21	368	487
% Agreement (Exact Match)	93.02	91.43	85.00	95.24	100.00	97.95
% Agreement (+/- Color Block)	100.00	100.00	100.00	100.00	100.00	100.00

Protein concentration levels compared at a 97.95% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

Urobilinogen						
Thunderbolt / Uritek-720+	>8.0	4	2	1	0.2	Overall
>8.0	10	1				
4.0	1	66	4			
2.0		1	27	1		
1.0				31	13	
0.2					332	
Total	11	68	31	32	345	487
% Agreement (Exact Match)	90.91	97.06	87.10	96.88	96.23	95.69
% Agreement (+/- Color Block)	100.00	100.00	100.00	100.00	100.00	100.00

Urobilinogen concentration levels compared at a 95.69% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

pH								
Thunderbolt / Uritek-720+	8.5	8	7.5	7.0	6.5	6.0	5.0	Overall
8.5	10							
8.0		12						
7.5			111	4	1			
7.0			3	59	2	1		
6.5				3	94	33		
6.0						64	18	
5.0						1	71	
Total	10	12	114	66	97	99	89	487
% Agreement (Exact Match)	100	100	97.37	89.39	96.91	64.65	79.78	86.45
% Agreement (+/- Color Block)	100	100	100.00	100.00	98.97	98.99	100.00	99.59

pH concentration levels compared at an 86.45% overall exact match and a 99.59% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

Nitrite			
Thunderbolt / Uritek-720+	+	-	Overall
+	70		
-	1	416	
Total	71	416	373
% Agreement (Exact Match)	98.59	100.00	99.79
% Agreement (+/- Color Block)	100.00	100.00	100.00

Nitrite concentration levels compared at a 99.79% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

Leukocyte						
Thunderbolt / Uritek-720+	3+	2+	1+	TRA	Neg	Overall
3+	12					
2+	1	17	4			
1+		5	27	5		
TRA			1	15		
Neg					400	
Total	13	22	32	20	400	487
% Agreement (Exact Match)	92.31	77.27	84.38	75.00	100.00	96.71
% Agreement (+/- Color Block)	100.00	100.00	96.88	100.00	100.00	100.00

Leukocyte concentration levels compared at a 96.71% overall exact match and a 100% overall agreement +/- one color block match between the TC-Thunderbolt Automated Urine Analyzer System and Uritek-720+ Analyzer.

C) Sensitivity/ Cutoff Point Determination Study Summary

- *Sensitivity Study*

Sensitivity Study was performed to determine the cutoff point concentration at which each analyte on the TC-Thunderbolt URS-10 strip changed from negative to the positive color blocks. Samples were prepared by spiking the specified analyte concentration into negative urine with a minimum of 4 levels across the measuring range for each color block. Each pool was then analyzed in replicates of 7 by 3 operators on each of the 3 individual strip lots (7 strips x 3 operators/ strip lots), for a total of 21 data points for each level. The cutoff point determination study for each color block for each analyte is defined as the lowest concentration at which >55% of the test results are positive.

Results:

The cut-off values and percentage sensitivity for each color block for individual analyte is summarized and demonstrated in the table below:

Analyte	Color Block	Cut-off Concentration	% Positive Results
Glucose	100 mg/dL	75 mg/dL	90%
	250 mg/dL	212.5 mg/dL	85%
	500 mg/dL	437.5 mg/dL	85%
	1000 mg/dL	875 mg/dL	85%
Bilirubin	Small	0.375 mg/dL	57%
	Moderate	1 mg/dL	100%
	Large	2.5 mg/dL	57%
Ketone	Trace	3.75 mg/dL	95%
	15 mg/dL	10 mg/dL	55%
	40 mg/dL	27.5 mg/dL	55%
	80 mg/dL	60 mg/dL	95%
Blood	Trace	0.023 mg/dL	61%
	Small	0.064 mg/dL	76%
	Moderate	0.199 mg/dL	90%
	Large	0.628 mg/dL	90%
Protein	Trace	11.25 mg/dL	75%
	30 mg/dL	26.25 mg/dL	85%
	100 mg/dL	82.5 mg/dL	95%
	300 mg/dL	200 mg/dL	85%
	2000 mg/dL	1150 mg/dL	70%
Nitrite	Positive	0.1 mg/dL	55%
Leukocyte	Trace	15 ca cells/µL	100%
	Small	56.25 ca cells/µL	95%
	Moderate	97.5 ca cells/µL	60%

	Large	406.25 ca cells/µL	55%
Urobilinogen	0.2 mg/dL	0.2 mg/dL	100%
	1.0 mg/dL	0.8 mg/dL	71%
	2.0 mg/dL	2.0 mg/dL	90%
	4.0 mg/dL	3.5 mg/dL	55%
	8.0 mg/dL	7.0 mg/dL	85%
pH	5.0	5.0	95%
	6.0	6.0	95%
	6.5	6.5	95%
	7.0	7.0	95%
	7.5	7.5	95%
	8.0	8.0	100%
	8.5	8.5	100%
SG	1.005	1.005	100%
	1.010	1.010	100%
	1.015	1.015	100%
	1.020	1.020	100%
	1.025	1.025	100%
	1.030	1.030	100%

The results for specific analyte concentration at each color block are shown below:

	Concentration Tested	Percentage Agreement at Each Color Block				
GLUCOSE		Negative	100 mg/dL	250 mg/dL	500 mg/dL	1000 mg/dL
	25 mg/dL	100%	0%	0%	0%	0%
	50 mg/dL	100%	0%	0%	0%	0%
	75 mg/dL	10%	90%	0%	0%	0%
	100 mg/dL	0%	100%	0%	0%	0%
	137.5 mg/dL	0%	100%	0%	0%	0%
	175 mg/dL	0%	100%	0%	0%	0%
	212.5 mg/dL	0%	15%	85%	0%	0%
	250 mg/dL	0%	0%	100%	0%	0%

	312.5 mg/dL	0%	0%	100%	0%	0%
	375 mg/dL	0%	0%	100%	0%	0%
	437.5 mg/dL	0%	0%	15%	85%	0%
	500 mg/dL	0%	0%	0%	100%	0%
	625 mg/dL	0%	0%	0%	100%	0%
	750 mg/dL	0%	0%	0%	60%	40%
	875 mg/dL	0%	0%	0%	15%	85%
	1000 mg/dL	0%	0%	0%	0%	100%

	Concentration Tested	Percentage Agreement at Each Color Block			
		Negative	Small	Moderate	Large
BILIRUBIN	0.125 mg/dL	100%	0%	0%	0%
	0.25 mg/dL	100%	0%	0%	0%
	0.375 mg/dL	43%	57%	0%	0%
	0.5 mg/dL	0%	100%	0%	0%
	0.625 mg/dL	0%	100%	0%	0%
	0.75 mg/dL	0%	100%	0%	0%
	0.875 mg/dL	0%	71%	29%	0%
	1 mg/dL	0%	0%	100%	0%
	1.5 mg/dL	0%	0%	100%	0%
	2 mg/dL	0%	0%	100%	0%
	2.5 mg/dL	0%	0%	43%	57%
	3 mg/dL	0%	0%	0%	100%

	Concentration Tested	Percentage Agreement at Each Color Block				
		Negative	Trace	15 mg/dL	40 mg/dL	80 mg/dL
KETONE	1.25 mg/dL	100%	0%	0%	0%	0%
	2.5 mg/dL	85%	15%	0%	0%	0%
	3.75 mg/dL	5%	95%	0%	0%	0%

	5 mg/dL	0%	100%	0%	0%	0%
	7.5 mg/dL	0%	100%	0%	0%	0%
	10 mg/dL	0%	45%	55%	0%	0%
	12.5 mg/dL	0%	10%	90%	0%	0%
	15 mg/dL	0%	0%	100%	0%	0%
	21.5 mg/dL	0%	0%	90%	10%	0%
	27.5 mg/dL	0%	0%	45%	55%	0%
	33.75 mg/dL	0%	0%	0%	100%	0%
	40 mg/dL	0%	0%	0%	100%	0%
	50 mg/dL	0%	0%	0%	60%	40%
	60 mg/dL	0%	0%	0%	5%	95%
	70 mg/dL	0%	0%	0%	0%	100%
	80 mg/dL	0%	0%	0%	0%	100%

	Concentration Tested	Percentage Agreement at Each Color Block				
		Negative	Trace	Small	Moderate	Large
BLOOD	0.008 mg/dL	90%	10%	0%	0%	0%
	0.015 mg/dL	81%	19%	0%	0%	0%
	0.023 mg/dL	29%	61%	0%	0%	0%
	0.03 mg/dL	0%	100%	0%	0%	0%
	0.043 mg/dL	0%	100%	0%	0%	0%
	0.053 mg/dL	0%	90%	10%	0%	0%
	0.064 mg/dL	0%	24%	76%	0%	0%
	0.075 mg/dL	0%	0%	100%	0%	0%
	0.116 mg/dL	0%	0%	100%	0%	0%
	0.158 mg/dL	0%	0%	100%	0%	0%
	0.199 mg/dL	0%	0%	10%	90%	0%
	0.24 mg/dL	0%	0%	0%	100%	0%
	0.368 mg/dL	0%	0%	0%	100%	0%

	0.495 mg/dL	0%	0%	0%	100%	0%
	0.628 mg/dL	0%	0%	0%	10%	90%
	0.75 mg/dL	0%	0%	0%	0%	100%

	Concentration Tested	Percentage Agreement at Each Color Block					
		Negative	Trace	30 mg/dL	100 mg/dL	300 mg/dL	2000 mg/dL
PROTEIN	3.75 mg/dL	100%	0%	0%	0%	0%	0%
	7.5 mg/dL	55%	45%	0%	0%	0%	0%
	11.25 mg/dL	25%	75%	0%	0%	0%	0%
	15 mg/dL	0%	100%	0%	0%	0%	0%
	18.75 mg/dL	0%	90%	10%	0%	0%	0%
	22.5 mg/dL	0%	20%	80%	0%	0%	0%
	26.25 mg/dL	0%	15%	85%	0%	0%	0%
	30 mg/dL	0%	0%	100%	0%	0%	0%
	47.5 mg/dL	0%	0%	100%	0%	0%	0%
	65 mg/dL	0%	0%	5%	95%	0%	0%
	82.5 mg/dL	0%	0%	5%	95%	0%	0%
	100 mg/dL	0%	0%	0%	100%	0%	0%
	150 mg/dL	0%	0%	0%	80%	20%	0%
	200 mg/dL	0%	0%	0%	15%	85%	0%
	250 mg/dL	0%	0%	0%	5%	95%	0%
	300 mg/dL	0%	0%	0%	0%	100%	0%
	725 mg/dL	0%	0%	0%	0%	55%	45%
	1150 mg/dL	0%	0%	0%	0%	30%	70%
	1575 mg/dL	0%	0%	0%	0%	10%	90%
	2000 mg/dL	0%	0%	0%	0%	0%	100%

	Concentration Tested (ca cells/μL)	Percentage Agreement at Each Color Block				
		Negative	Trace	Small	Moderate	Large
LEUKOCYTES	3.75	100%	0%	0%	0%	0%
	7.5	100%	0%	0%	0%	0%
	11.25	95%	5%	0%	0%	0%
	15	0%	100%	0%	0%	0%
	28.75	0%	95%	5%	0%	0%
	42.5	0%	80%	20%	0%	0%
	56.25	0%	5%	95%	0%	0%
	70	0%	0%	100%	0%	0%
	83.75	0%	0%	100%	0%	0%
	97.5	0%	0%	40%	60%	0%
	111.25	0%	0%	0%	100%	0%
	125	0%	0%	0%	100%	0%
	218.75	0%	0%	0%	100%	0%
	312.5	0%	0%	0%	100%	0%
	406.25	0%	0%	0%	45%	55%
	500	0%	0%	0%	0%	100%

	Concentration tested	Percentage Agreement at Each Color Block	
NITRITE		Negative	Positive
	0.025 mg/dL	100%	0%
	0.05 mg/dL	100%	0%
	0.075 mg/dL	100%	0%
	0.1 mg/dL	45%	55%

	Concentration Tested (mg/dL)	Percentage Agreement at Each Color Block				
UROBILINOGEN		0.2	1	2.0	4.0	8.0

	0.2	100%	0%	0%	0%	0%
	0.4	100%	0%	0%	0%	0%
	0.6	100%	0%	0%	0%	0%
	0.8	29%	71%	0%	0%	0%
	1.0	0%	100%	0%	0%	0%
	1.25	0%	100%	0%	0%	0%
	1.5	0%	90%	0%	0%	0%
	1.75	0%	62%	28%	0%	0%
	2.0	0%	10%	90%	0%	0%
	2.5	0%	0%	100%	0%	0%
	3.0	0%	0%	100%	0%	0%
	3.5	0%	0%	45%	55%	0%
	4.0	0%	0%	0%	100%	0%
	5.0	0%	0%	0%	100%	0%
	6.0	0%	0%	0%	80%	20%
	7.0	0%	0%	0%	15%	85%
	8.0	0%	0%	0%	0%	100%

	Concentration Tested	Percentage Agreement at Each Color Block						
		5.0	6.0	6.5	7.0	7.5	8.0	8.5
pH	5.0	95%	5%	0%	0%	0%	0%	0%
	6.0	5%	95%	0%	0%	0%	0%	0%
	6.5	0%	0%	95%	0%	0%	0%	0%
	7.0	0%	0%	5%	95%	0%	0%	0%
	7.5	0%	0%	0%	5%	95%	0%	0%
	8.0	0%	0%	0%	0%	5%	100%	0%
	8.5	0%	0%	0%	0%	0%	5%	100%

	Concentration Tested	Percentage Agreement at Each Color Block					
SG		1.005	1.010	1.015	1.020	1.025	1.030

	1.000	100%	0%	0%	0%	0%	0%
	1.005	100%	0%	0%	0%	0%	0%
	1.010	0%	100%	0%	0%	0%	0%
	1.015	0%	0%	100%	0%	0%	0%
	1.020	0%	0%	0%	100%	0%	0%
	1.025	0%	0%	0%	0%	100%	0%
	1.030	0%	0%	0%	0%	0%	100%

D) Linearity Study/ Assay Reportable Range Study Summary:

The linear range of TC-Thunderbolt Automated Urine Analyzer was evaluated by measuring negative urine and negative urine spiked with known increasing and decreasing concentrations of analytes relative to each color block covering the entire measuring range of each analyte present on the TC-Thunderbolt URS-10 strip. Sample measurement was performed in replicates of 7 by 3 operators on each of 3 individual strip lots (7 strips x 3 operators/ strip lots), for a total of 21 measurements for every sample tested. A pH meter was used to confirm the pH results. The specific gravity values were confirmed by a clinical, handheld refractometer. A specific gravity reading of 1.000 was obtained from distilled water. Specific gravity measurements were performed in replicates of 7 by 3 operators on each of 3 individual strip lots (7 strips x 3 operators/ strip lots), for a total of 21 measurements for every sample tested.

Results:

The linear range of the TC-Thunderbolt Automated Urine Analyzer is summarized in the table below:

Analyte	TC-Thunderbolt Output Block	Measuring Range
Glucose	Negative	0.0 – 75 mg/dL
	100 mg/dL	75 – 212.5 mg/dL
	250 mg/dL	212.5 – 437.5 mg/dL
	500 mg/dL	437.5 – 875 mg/dL
	1000 mg/dL	> 875 mg/dL
Bilirubin	Negative	0.0 – 0.375 mg/dL
	Small	0.375 – 1.0 mg/dL
	Moderate	1.0 – 2.5 mg/dL
	Large	> 2.5 mg/dL
Ketone	Negative	0.0 – 3.75 mg/dL
	Trace	3.75 – 10.0 mg/dL
	15 mg/dL	10.0 – 27.5 mg/dL
	40 mg/dL	27.5 – 60.0 mg/dL
	80 mg/dL	> 60.0 mg/dL
Blood	Negative	0.0 – 0.023 mg/dL
	Trace	0.023 – 0.064 mg/dL

	Small	0.064 – 0.199 mg/dL
	Moderate	0.199 – 0.628 mg/dL
	Large	> 0.628 mg/dL
Protein	Negative	0.0 – 11.25 mg/dL
	Trace	11.25 – 26.25 mg/dL
	30 mg/dL	26.25 – 82.5 mg/dL
	100 mg/dL	82.5 – 200 mg/dL
	300 mg/dL	200 – 1150 mg/dL
	2000 mg/dL	> 1150 mg/dL
Nitrite	Negative	0.0 – 0.1 mg/dL
	Positive	> 0.1 mg/dL
Leukocyte	Negative	0.0 – 15 ca cells/µL
	Trace	15 – 56.25 ca cells/µL
	Small	56.25 – 97.5 ca cells/µL
	Moderate	97.5 – 406.25 ca cells/µL
	Large	> 406.25 ca cells/µL
Urobilinogen	0.2 mg/dL	0.2 – 0.6 mg/dL
	1.0 mg/dL	0.8 – 1.5 mg/dL
	2.0 mg/dL	2.0 – 3.0 mg/dL
	4.0 mg/dL	3.5 – 6.0 mg/dL
	8.0 mg/dL	7.0 – 8.0 mg/dL
pH	5.0	5.0
	6.0	6.0
	6.5	6.5
	7.0	7.0
	7.5	7.5
	8.0	8.0
	8.5	8.5
SG	1.005	1.005
	1.010	1.010
	1.015	1.015
	1.020	1.020
	1.025	1.025
	1.030	1.030

E) Analytical Specificity and Interference

Interfering substance studies were performed to assess the interfering effect of various substances on the TC-Thunderbolt URS-10 strips used on the TC-Thunderbolt Automated Urine Analyzer. Urine sample pools were prepared at 2 concentrations for each urine chemistry analyte; negative and positive. The negative sample pools had no analyte present while the positive sample pools were prepared by spiking each analyte into negative urine at the concentrations listed below:

Concentration of Samples Tested

Analyte	Concentrations to be Tested		
	Negative	Positive	Unit
Glucose	0	100	mg/dL
Protein	0	30	mg/dL
Bilirubin	0	0.5	mg/dL
Urobilinogen	0	2	mg/dL
pH	6.0	7.0	-
Blood	0	0.24	mg/dL
Ketone	0	15	mg/dL
Nitrite	0	0.10	mg/dL
Leukocytes	0	125	ca Cells/µL

Each urine sample was tested with 3 replicates using TC-Thunderbolt Urine Analyzer System and a mean result was calculated. The mean result from samples with no interfering substance was compared against the mean result of the sample spiked with the interfering substance at the stated concentration. Interference was defined as a change in output of ± 1 color blocks between spiked and unspiked control sample. For pH, interference was defined as a change of ± 2 color blocks between the spiked and unspiked control sample.
The concentrations of the potential interfering substances that did not have any influence on the test results are listed below:

Potential Interfering Substance	Highest Concentration of substance tested which demonstrated no Interference
Ascorbic Acid	10 mg/dL
Ammonium Chloride	400 mg/dL
Albumin	300 mg/dL
Bilirubin	4 mg/dL
Calcium Chloride	80 mg/dL
Citric Acid	65 mg/dL
Creatinine	600 mg/dL
D (+) Glucose	500 mg/dL
Glycine	900 mg/dL
Hemoglobin	0.3 mg/dL
Potassium Chloride	1000 mg/dL
Sodium Chloride	2000 mg/dL
Oxalic Acid	20 mg/dL
Sodium Nitrate	10 mg/dL
Sodium Nitrite	0.5 mg/dL
Sodium Phosphate	1000 mg/dL
Urea	3000 mg/dL
D (+) Galactose	300 mg/dL

Tetracycline	100 mg/dL

The following table shows the substances which did interfere with one or more of the TC-Thunderbolt URS-10 analytes. Results are expressed as the lowest concentration of interfering substance that exhibited interference and the resulting change in output of color block.

Analyte	Concentration of Substance at which Interference was observed	Change in Color block Output
Glucose	Ascorbic Acid ≥ 30 mg/dL	-1
Protein	Hemoglobin ≥ 50 mg/dL, D(+) Glucose ≥ 2000 mg/dL	+1, -1
Bilirubin	Ascorbic Acid ≥ 30 mg/dL, MESNA ≥ 50 mg/dL, Sodium Nitrite ≥ 2 mg/dL, Sodium Nitrate ≥ 10 mg/dL, D(+) Glucose ≥ 2000 mg/dL	-1
Urobilinogen	--	--
Blood	Albumin ≥ 1000 mg/dL, Ascorbic Acid ≥ 30 mg/dL	+1, -1
Nitrite	D(+) Glucose ≥ 2000 mg/dL	-1
Leukocytes	D(+) Glucose ≥ 2000 mg/dL, Ascorbic Acid ≥ 30 mg/dL	-1
Ketone	MESNA ≥ 50 mg/dL,	+3
pH	Acetoacetate ≥ 60 mg/dL, Oxalic Acid ≥ mg/dL, Citric Acid ≥ 130 mg/dl	+1, -1, -1

Based on the results of this testing the sponsor has included the effects from above interfering substances in the labeling as limitations of procedure.

4.10) Shelf Life Studies:

A) Accelerated Stability Study Summary

Accelerated study was performed on closed bottles of TC-Thunderbolt URS-10 strips as a means of assessing the shelf-life of the closed product, which is verified in real time studies. This study involves testing the device once per week periodically, for the duration of the study using Urine Control Solutions Levels I, II and III. TC-Thunderbolt URS-10 bottles used in the Stressed Study will have passed Quality Control inspection and stored at 37°C ± 2°C.

Acceptance Criteria:

The TC-Thunderbolt URS-10 strips must pass Quality Control testing for ≥ 90 days to confirm the closed bottle shelf life of two (2) years at room temperature (15-30°C) with 20-30% humidity.

Results:

Three lots of TC-Thunderbolt URS-10 strips all passed Quality Control testing for 91 days at 37°C ± 2°C. The expected shelf life of the TC-Thunderbolt URS-10 strips is 28 months based on the Accelerated Stability Study Test Results.

B) Real-time Stability Study Summary:

A real time, temperature and humidity stability study is currently being performed on closed bottles of TC-Thunderbolt URS-10 strips to validate the claims stated in the Stress Stability Studies. This study involves testing the TC-Thunderbolt URS-10 strips using Urine Control Solutions Levels I, II and III for every six (6) months from the manufactured date, until 18 months. After the TC-Thunderbolt URS-10 strips has passed 18 months, test every three (3) months until the product fails or until 28 months. Three (3) lots of TC-Thunderbolt URS-10 strips used in the Real Time Shelf Life Study will have passed Quality Control inspection and are being kept at room temperature (15-30°C) and 20-30% humidity.

Acceptance Criteria: The product must pass Quality Control testing in real-time through its expiration date in the conditions that the product will be stored: closed bottle, room temperature (15-30°C)

Result:
This study is currently on-going. The three lots of TC-Thunderbolt URS-10 strips have passed the 12 months Quality Control testing and we plan to continue testing until 28 months.

C) Open-vial Stability Study Summary:

Open-vial Study was performed on opened bottles (broken seal) of TC-Thunderbolt URS-10 strips as a means of assessing the shelf-life of the opened bottle product once the seal is broken. This study involves testing the device once per week periodically, for the duration of the study using Urine Control Solutions Levels I, II and III. TC-Thunderbolt URS-10 bottles used in the Open-vial Study will have passed Quality Control inspection and are opened (seals broken) and stored at room temperature (15-30°C) and 20-30% humidity.

Acceptance Criteria:
The TC-Thunderbolt URS-10 strips must pass Quality Control testing for ≥ 90 days to confirm the opened bottle shelf life of 3 months at room temperature (15-30°C) with 20-30% humidity.

Result:
Three lots of Open Vial TC-Thunderbolt URS-10 strips all passed Quality Control testing for 91 days at 15-30°C. The expected shelf life of the Open Vial TC-Thunderbolt URS-10 strips is 90 days based on the Open Vial Stability Study Test Results.

4.11) Conclusion:

The performance characteristics of the TC-Thunderbolt Automated Urine Analyzer System were verified by method comparison, precision, sensitivity and cutoff point determination, linearity/ assay reportable range, analytical specificity and interference, shelf life and stress studies. Testing results indicate that the TC-Thunderbolt Automated Urine Analyzer System perform satisfactorily when used appropriately, as outlined in the package insert.